IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

KYOWA HAKKO BIO, CO., LTD., BIOKYOWA, INC., KYOWA HAKKO BIO U.S. HOLDINGS, INC., and KYOWA HAKKO U.S.A., INC.,
Plaintiffs,

v.

AJINOMOTO CO., INC., AJINOMOTO HEALTH & NUTRITION NORTH AMERICA, INC., and AJINOMOTO FOODS NORTH AMERICA, INC.,
Defendants.

Civil Action No. 17-cv-00313-MSG

Jury Trial Demanded

REDACTED VERSION

AJINOMOTO'S ANSWERING CLAIM CONSTRUCTION BRIEF

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Exhibits 29– 39 are attached to the Declaration of Lisa Mandrusiak in Support of Ajinomoto's Answering Claim Construction Brief ("Mandrusiak Decl.") submitted herewith.

Ex. 1 RE 45,723 ("the '723 patent").

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Ex. 3 File History of the '723 patent, KHB_0000374–1327.

Ex. 4 Perry's Chemical Engineers' Handbook, § 20-6 (7th ed. 1997), AJ110388–90.

Ex. 5 Particle size analysis – Laser diffraction methods – Part 1: General principles, International Standard, ISO 13320-1 (1st ed. 1999), AJ109016–56.

Ex. 6 Dr. Alan Rawle, Basic Principles of Particle Size Analysis, Technical Paper, MRK034, Malvern Instruments (2003) (color version).

Ex. 7 Horiba, A Guidebook to Particle Size Analysis (2012) (color version).

Ex. 8 Allan S. Myerson, Handbook of Industrial Crystallization, Chaps. 1, 2 & 4 (2d ed. 2002).

Ex. 9 Philip Plantz, Explanation of Data Reported by Microtrac Instruments, Applications Note, SL-AN-16 Ref F, Microtrac Inc. (2008), AJ108991–97.

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Introduction

All relevant, intrinsic evidence supports Ajinomoto's proposed construction that the average particle size is the volume mean diameter, known as D[4,3] or MV, or else it is indefinite. Kyowa ignores the values in Fig. 1 of the '723 patent—the lone example in the patent that shows the relationship between the average particle size and specific surface area of the added crystals—and will be forced to discredit its own patent to sustain its argument. Similarly, Kyowa must distance itself from the Rawle and Horiba references it submitted in the patent's file history because they conflict with the vocabulary advocated by Kyowa's new technical expert to explain away unfavorable evidence. Further, Kyowa's construction of "average particle size" is directly contradicted by pre-litigation admissions and testimony of Kyowa, its previous technical experts, [redacted] and the inventors of the '723 patent.

Conscious of these significant problems, Kyowa attempts to create a back-up infringement argument by improperly broadening the step of "adding crystals … to the medium" to include crystals that nucleate or break off from the amino acid that is *already in* the medium. But the '723 patent precludes Kyowa's position by consistently and repeatedly demonstrating that "adding" refers only to the external crystals that are carefully prepared to have a certain average particle size and are subsequently put in the medium. The patent never bases the average-particle-size calculations on the crystals that are nucleating or breaking up within the medium. Indeed, Kyowa's new expert could not even speculate as to how average particle size could be measured if "adding" encompassed nucleation and breakage of crystals within the medium, as there is simply no guidance or support in the specification for such a measurement.

Argument

A. The intrinsic record directly supports Ajinomoto's construction of "average particle size" and offers no support for Kyowa's construction.

The parties do not dispute that "average particle size" must be qualified with explanatory terms not found in the '723 patent. Ajinomoto uses the word "volume," whereas Kyowa uses the word "arithmetic." This is out of necessity, as admitted by Kyowa, because various types of averages can yield "wildly different results." (Kyowa Br., p.7.) While Ajinomoto's proposed construction is rooted in Fig. 1 of the patent and the references in the intrinsic record, Kyowa relies primarily on extrinsic evidence in the form of piecemeal dictionary definitions and the say-so of its new expert, Dr. Michael Doherty. Significantly, Kyowa finds no direct support for its claim construction positions in the intrinsic record.

1. Dr. Doherty's own calculations independently demonstrate that Fig. 1 precludes Kyowa's construction.

When Dr. Doherty read the patent, "virtually the first thing" he did was to calculate the average particle size of the crystals in the photograph for experiment 4 in Fig. 1. (Ex. 29, p. 29:19–30:4.) His deposition revealed that he calculated an arithmetic mean diameter of 81 μm, far below the reported value of 110 μm in Fig. 1. (Ex. 29, p. 31:8–11; Ex. 36; Ex. 37, showing creation and modification dates of Dr. Doherty's measurements.) Thus, like Dr. Myerson's analysis of Fig. 1 that shows mathematically how the specific-surface-area measurements rule out Kyowa's proposed claim construction, Dr. Doherty's measurements of the crystals in Fig. 1 also rule out Kyowa's construction. Understandably, neither Kyowa's opening brief nor Dr. Doherty's declaration reports the 81-μm result:

> Q. Why didn't you report the results of your image analysis in your declaration?
> A. I have no answer for that.
>
> (Ex. 29, Doherty Tr., p. 34:6–8.)

To downplay the significance of Dr. Doherty's measurements, Kyowa will presumably argue that the 110-µm value in Fig. 1 is not the average particle size because Fig. 1 uses the row heading "Particle size of crystals added (µm)" without the word "average." That is not credible. The only particle size mentioned in the '723 patent is the average particle size, and the '723 patent twice states that Fig. 1 shows the average particle size. (Col. 2:62–64, 9:64–67; Ex. 32, p. 88:9–89:8, 91:2–6.)

2. Ajinomoto's proposed construction originates from publications within the file history that Dr. Doherty characterized as relevant and reliable.

Kyowa criticizes Ajinomoto's proposal—average particle size is the volume mean diameter—as vague. (Kyowa Br., p. 15.) But Ajinomoto's construction is taken directly from the intrinsic record, in particular, from the Rawle and Horiba references: Rawle refers to "D[4,3] or equivalent volume mean" and the "volume mean size" (Ex. 6, p. 3), and Horiba states that "the volume mean diameter has several names including D4,3" (Ex. 7, p. 4). Moreover, these references explain that the volume mean diameter, D[4,3], is the most common way to express laser diffraction results—the only measurement technique described in the '723 patent. (Ex. 6, p. 3; Ex. 7, p. 11; *see also* Ex. 32, p. 21:15–22, 22:25–23:6, 78:6–12.)

Moreover, Dr. Doherty vouched for the Rawle and Horiba references at his deposition, acknowledging that they are "relevant and reliable for purposes of claim construction in this case." (Ex. 29, p. 11:17–20; *see also* Ex. 32, p. 136:21–137:12.) But once Dr. Doherty understood that Horiba undermined his conclusions, he complained that it and other references were "sloppy" (Ex. 29, p. 84:21–85:10), even though Horiba and Rawle were the only references containing an explanation of average particle size that Kyowa submitted to the Patent Office during prosecution.

Further, a small portion of J.W. Mullin's *Crystallization* is cited on the face of the patent. In a

different portion of the book, Mullin observes, "The volume mean diameter … is widely used," and he defines the volume mean diameter as D[4,3]. (Ex. 29, p. 44:5–19; Ex. 30, Mullin, p. 77; *see also* Ex. 32, p. 45:16–46:7; 131:10–24; 216:10–217:3.) When confronted with Mullin, Dr. Doherty replied, out of necessity, "I think Mullin is sloppy." (Ex. 29, p. 85:2–3.)

Because there is explicit support in the intrinsic record supporting Ajinomoto's construction, there is nothing vague or unusual about Ajinomoto's proposed construction.

3. The volume mean diameter better serves the objectives of the claimed process.

Ajinomoto and Kyowa agree that the '723 patent stresses the importance of adding seed crystals with sufficient total surface area to allow adequate crystal growth. (Kyowa Br., p. 10.) The parties further agree that larger crystals have less surface area per unit of mass or volume than smaller crystals and should be avoided to the extent that large crystals constitute a significant amount of the added seed-crystal mass. In Dr. Doherty's words, large particles "pollute the seeds" because they "take up precious mass." (Ex. 29, p. 60:23–61:7.) For these reasons, smaller particles make for better seeds than larger particles. (*Id*.)

It makes sense, then, that the better measure of average particle size is the one that is more sensitive to the presence of undesirable large particles. (Ex. 7, p. 11.) That measure is, undisputedly, the volume mean diameter because it tells you "where most of the volume of the set lies." (Kyowa Br., p. 16.) And, the intrinsic record confirms this property of the volume mean diameter. Rawle cautions, "So the number mean does not accurately reflect where the mass of the system lies. This is where the D[4,3] is more useful. … This value shows us more where the mass of the system lies and is of more value to chemical process engineers." (Ex. 6, p. 4.) Likewise, Horiba observes that the number mean can be too insensitive to changes in the larger particles: "Care should be taken to avoid basing specifications on the number-based mean since this value may not track process changes such as milling." (Ex. 7, p. 14.) Accordingly, Horiba

recommends, "It is a good idea to use or include the D4,3 in the specification if product performance is sensitive to the presence of large particles." (Ex. 7, p. 11.)

Although the volume mean diameter best describes the size that constitutes most of the seed crystal mass/volume, Kyowa nonetheless argues that "the purpose of this specific [claimed] particle size range is to ensure that ***the individual crystals*** in the seed-crystal set are the ideal size." (Kyowa Br., p. 16, emphasis in original). This contradicts the text of the patent, which, starting at starting at column 5, line 15, specifies two processes for controlling the seed crystals. In process (1), the average particle size is controlled in combination with the total mass of crystals "to be added" to achieve a "concentration of 0.5 g/l or more" (col. 5:60–65), and in process (2) "there is no restriction on the average particle size, the amount … etc. of the crystals so far as the total surface area of the crystals of the amino acid in the medium becomes 0.02 m^2/l or more" (col. 7:3–27). Thus, average particle size is not an end unto itself but a means to an optimized concentration or surface area. (D.I. 84, Doherty Decl. ¶ 22, 29.)

To support its position that average particle size is the sum of particle sizes divided by the number of particles, Kyowa points to an excerpt in the patent that contains the word "number":

> … the particle size of crystals of an amino acid deposited in the medium during the culturing can be controlled by adding crystals of the amino acid to the medium to keep the degree of supersaturation of the amino acid in the medium below a certain level and to allow an appropriate *number* of crystals of the amino acid to be present in the medium as seed crystals that is, by adjusting the average particle size and the amount or the total surface area of the crystals of the amino acid to be added to the medium …. (Col. 10:33–38, emphasis added.)

But, nothing in that passage suggests that individual seed crystals are counted or that the average particle size is determined by counting the number of crystals. At most, the passage merely reiterates the patent's disclosure that the crystals "to be added to the medium" must be controlled on the basis of (1) average particle size and amount or (2) total surface area.

Further, the "amount" of crystal added in the process (1) is consistently described and claimed as a concentration in grams per liter, *i.e.*, mass per unit of volume—not the number of crystals. (*See, e.g.,* col. 6:3–8; 10:55–56.) In other words, the average particle size *and* total mass of the seed crystals has to be adjusted to obtain an effective concentration of seed crystals. Because the volume mean and the mass mean are equal for a substance with fixed density (Ex. 29, p. 47:16–20), the volume mean diameter indicates whether the seed-crystal mass is centered on a particle size within the effective range. On the other hand, the arithmetic mean (sum of diameters divided by the number of particles) fluctuates with the number of small particles and is not a good indicator of whether the seed-crystal mass is centered within the effective size range. (*See* Ex. 32, p. 117:12–19; 141:21–142:7.) Simply put, the volume mean is better than the arithmetic mean at indicating whether most of the total crystal mass has the desired size.

The importance of the volume mean diameter is highlighted by Kyowa's own example of a "pebble-sized" crystal. (Kyowa Br., p. 18–19.) Out of the 1,000,001 seed crystals in the example, the single 1-centimeter crystal constitutes over 99% of the total mass or volume. Thus, even if there is enough total crystal mass to achieve the desired concentration in grams per liter, nearly the entire amount is wasted because it exceeds the maximum effective size. The arithmetic mean (sum of diameters divided by the number of particles = 10 μm) conceals that problem, while the volume mean diameter (D[4,3] = 1 cm = *10,000 μm*) exposes it.

Likewise, Kyowa's citation to Rawle's example of making gold (Kyowa Br., p. 18), supports Ajinomoto's proposed construction with respect to the grown crystals "having an average particle size of 30 μm or more" in the claims. In the Rawle example, the smaller gold particles can be disregarded because they constitute a small percentage of the overall mass or volume of the gold product. The same logic applies to the recovery of the grown crystals in claims 1 and 2

of the patent. When the crystals have grown to “an average particle size of 30 μm or more,” a skilled artisan would not care about the *number* of crystals that are recoverable from the medium. (Col. 2:40–44.) Instead, a skilled artisan would want to know how much crystal mass (or volume) is recoverable. This is why Rawle observes that the arithmetic mean “does not accurately reflect where the mass of the system lies” and that the volume mean diameter “is much more useful.” (Ex. 6, p. 4.) In the context of crystal yields, even Dr. Doherty couldn’t deny that volume mean diameter, D[4,3], is the most common measure of particle size. (Ex. 29, p. 46:13–23, 85:25–86:8.)

Kyowa’s citations to *Osram*[1] do not move the needle. (Kyowa Br. 16, 19.) While *Osram* appears facially similar, its facts are distinguishable and the principle of law that it stands for is not what Kyowa proffers. The Federal Circuit did not give patentees a license to hide the ball with respect to a measurement, but instead concluded that a skilled artisan could select the measurement most appropriate for the objectives of the invention. In *Osram*, this was a straightforward process because “[a]ll of the experts agreed that the volume-based measure is more sensitive to large particles, which do not function in the invention, and that the number-based measure is more sensitive to the size and distribution of the particles that perform the inventive function.” 505 F.3d at 1357. Further, the focus was on whether an artisan could see through the patent’s ambiguity because only one measure functioned in accord with the invention. This case presents a different situation. The volume mean diameter serves the purposes of the invention and cannot be eliminated on the basis of the patent’s objectives.

[1] *Osram GmbH v. Int'l Trade Comm'n*, 505 F.3d 1351, 1357 (Fed. Cir. 2007).

Kyowa's citation to *Takeda*[2] is similarly unhelpful. Kyowa cites *Takeda* for the proposition that "a claim need not specifically list a measurement method for that method to fall within the claim's scope." (Kyowa Br., p. 23.) But, again, this is only true if the ambiguity does not defeat the objectives of the patent. In *Takeda,* "the evidence established that both methods of measurement accurately report average particle diameter" and "there is no evidence that the differences between these techniques are in fact significant." 743 F.3d at 1367. This is not the case here. The objective of the '723 patent—improving yield—is directly impacted by the surface area of seed crystals added, and the selection of one average particle size over another can, as Kyowa itself admits, produce "wildly different results."

In any event, because the '723 patent is directed to a commercial process that improves yield by controlling seed-crystal size, the volume mean diameter is an important measure of size because it indicates whether or not most of the seed-crystal volume/mass falls within the effective size range. On the other hand, the number average will not reflect the presence of larger, less effective particles that "take up precious mass." Therefore, one of ordinary skill in the art would have understood that, in the context of the patent, the volume mean diameter, D[4,3], is a better indicator of the effectiveness of a batch of seed crystals than the sum of particle diameters divided by the number of particles, D[1,0]. (*See* Ex. 32, p. 116:22–117:11.)

B. Ajinomoto's extrinsic evidence is far more relevant to the construction of "average particle size" than Kyowa's.

The extrinsic evidence overwhelmingly favors Ajinomoto's construction of average particle size. Other than the statements of its new expert, Kyowa's extrinsic evidence does not directly address the disputed term of art, "average particle size," and does not bear directly on the invention. On the other hand, Ajinomoto's extrinsic evidence addresses the entire phrase

[2] *Takeda Pharm. Co. v. Zydus Pharm. USA, Inc.*, 743 F.3d 1359, 1367 (Fed. Cir. 2014).

"average particle size" and includes Kyowa's pre-litigation admissions about the meaning of "average particle size" in the context of the same invention.

1. Kyowa's dictionary definitions do not address "average particle size."

Kyowa presumes "average" should be construed separately from "particle size" and relies on definitions of "average" and "arithmetic mean." (Kyowa Br., p.14–15.) Consequently, none of Kyowa's definitions addresses the entire claimed phrase "average particle size," which even Dr. Doherty characterizes as a term of art. (Ex. 29, p. 41:9–11.) The literature uses that term of art in a manner consistent with Ajinomoto's proposed construction and inconsistent with Kyowa's:

- *Perry's Chemical Engineer's Handbook* contains an entry for "average particle size" with three examples, one of which is D[4,3] and none of which is the sum of diameters divided by the number of particles. Dr. Doherty acknowledged this but tried to downplay *Perry's* as "sloppy." (Ex. 29, p. 41:15–42:3; Ex. 31, p. 20-6.)
- Horiba points out that "average particle size" has to be specified and observes that "average size" specifications most commonly use D[4,3] for laser diffraction measurements. (Ex. 7, p. 10–11.) Horiba recommends that D[4,3] should be used or included when performance is sensitive to large particles and that "[t]he other mean value that is occasionally used is the D3,2." (Ex. 7, p. 11.)
- The Microtrac Applications Note refers to MV or D[4,3] as "one type of average particle size." (Ex. 9, p. 3.) Dr. Doherty agreed that the Microtrac Applications Note was a "reliable source of intrinsic evidence" (he cited it in his declaration) but subsequently tried to downplay it ("I think it's sloppy") when he realized that it characterized D[4,3] as an average particle size. (Ex. 29, p. 48:13–16, 49:3–24.)

Because Kyowa's dictionary definitions fail to define the entire term of art that the patent actually uses, they are less relevant than *Perry's*, Horiba, and the Microtrac Applications Note, which use the entire term and apply it in the context of particle-size measurements. Those references not only show that "average particle size" can have different meanings but also that the volume mean diameter, D[4,3], is the one most relevant to the patent.

2. [redacted] undermine its position that volume mean diameter is not relevant to average seed crystal size.

On the day that the parties filed their opening claim-construction briefs, the parties jointly filed a stipulation of facts that Kyowa represents as true. (D.I. 78.) Through this stipulation, Kyowa represented [redacted]

[redacted] in stark contrast to the arguments on pages 16–19 of its opening brief. There, Kyowa takes the position that the volume mean diameter "does not calculate a number relevant to average seed crystal size." Dr. Doherty goes even further, declaring that "the volume-weighted mean diameter is not used to estimate the average size of seed particles." (D.I. 84, Doherty Decl. at ¶ 64.) These positions are flatly contradicted and undermined by [redacted]

Presumably, Kyowa will try to repair these contradictions by somehow arguing that the arithmetic mean (referred to as "MN" in Microtrac measurements) is a single-number substitute for [redacted] This cannot be the case, however, because Kyowa admits in its opening brief that number averages and weighted averages "can give wildly different results" and "have distinct

statistical purposes." (Kyowa Br., p. 7.) This outcome is reflected in [redacted] (Ex. 19 at KHB_0001363–70.)

3. Kyowa's pre-litigation admission that "average particle size" is volume-based and measured by laser diffraction is far more relevant than publications unrelated to the patent.

The statements that Kyowa and its experts made to the European Patent Office (EPO) prior to the commencement of this litigation are particularly significant to claim construction because they were made for the purpose of defining "average particle size" in the context of the same invention. In fact, Kyowa's European and U.S. patents—EP1870476 and the '723 patent—result from the same English-language translation of a Japanese priority patent application. (Ex. 1; Ex. 3 at KHB_0000379–401; Ex. 11 at AJ109148–69; Ex. 24.)

To the extent that Kyowa presents extrinsic evidence in the form of technical standards or journal articles, none is as relevant as Kyowa's and its experts' statements about the same disputed term in the same patent specification. For example, Kyowa cites to the ASTM and ISO standards, which merely identify 22+ ways to define average particle size. (Kyowa's Br., p. 14; *see*, *e.g.*, Ex. 15, p. 4–5; Ex. 32, p. 45:16–46:7.) On the other hand, Kyowa's and its experts' admissions to the EPO about the same patent specification address the identical issues in dispute here, namely, whether the average particle size is volume-weighted and whether it is measured by laser diffraction (emphasis added below):

- "[T]he analyzer mentioned in the opposed patent in fact measures the particle size based on *laser diffraction*." (Kyowa, Ex. 11 at AJ110437.)
- "[B]y selecting a certain technology for measuring the particle size also *the kind of average is fixed*." (Kyowa, Ex. 11 at AJ110438.)
- "[T]he opposed patent both is clear and provides sufficient information for a skilled person with regard to the parameter 'average particle size', i.e. *its meaning and the method for measuring it*." (Kyowa, Ex. 11 at AJ110439.)

- "Although reference is made to measuring 'specific surface area' in [the specification], it is clear that the commercial analyzer used *measures particle size distribution based on laser diffraction measurements*." (Kyowa's expert Dr. Rousseau, Ex. 11 at AJ110469.)
- "[S]ince the particle sizing was done by laser diffraction and no indication to the contrary is found in the patent, I assume that the *average was a volume-weighted quantity*." (Kyowa's expert Dr. Rousseau, Ex. 11 at AJ110469, in response to the question, "what kind of average is meant by 'average particle size'".)
- "[I]f there is one technology named to measure particle sizes (in EP1870476 B1 laser diffraction …) and there is an instrument given … then the results as an outcome are clear since the characteristics for the *particle measurements are then also fixed and the follow up calculations are fixed*, too. The 'mean size' of such a measurement results from the mean size of the size distribution given …." (Kyowa's expert Dr. Ulrich, Ex. 11 at AJ110510–11.)

Less stunning than these admissions (but relevant nonetheless), the same first-named inventor appears in another Kyowa patent, which states that the "Average Particle Diameter [] is synonymous with volume median diameter" of crystals. (Ex. 17, col. 8:1–6.) Kyowa is expected to argue that this volume-weighted measurement refers to the recovered crystals at the end of the process and not the seed crystals. Even so, there is no reason why one of ordinary skill in the art would measure seed crystals one way and recovered crystals another way because their comparison would be meaningless. The '723 patent itself describes and claims both the average particle size of seed crystals and the average particle size of the recovered crystals that have grown and accumulated. (Col. 9:47–57, 10:50–65.) And, Dr. Doherty agreed that the term "average particle size" is used consistently to mean the same thing throughout the '723 patent, including the claims. (Ex. 29, p. 18:2–20.) Thus, there is no basis for Kyowa to argue that the size of seed crystals is calculated one way and the size of recovered crystals is calculated another way, unless of course, that argument is litigation-driven.

In view of the weakness of Kyowa's evidence submitted with its opening brief, Ajinomoto anticipates that Kyowa's answering brief will cite to a stack of journal articles that report seed-

crystal measurements using the arithmetic mean. But, any such examples will still be less relevant than Kyowa's and its experts' pre-litigation admissions regarding the patent specification and [redacted]. Further, the statements of Kyowa and its original experts were made without the benefit of discovery in this lawsuit. By contrast, Dr. Doherty was retained by Kyowa after the completion of infringement-related discovery, presumably to replace Dr. Rousseau, who has not visibly participated in this case since attending the deposition of Ajinomoto's corporate witness. (Ex. 29, p. 11:21–25.)

Accordingly, Ajinomoto's extrinsic evidence is more relevant to how a skilled artisan would understand the entire term of art, "average particle size," than Kyowa's extrinsic evidence.

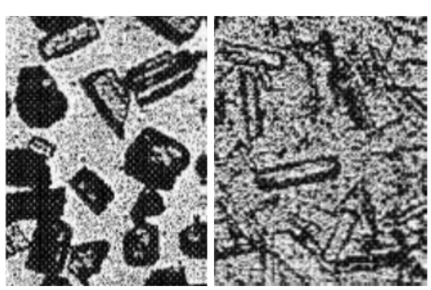
C. Kyowa's construction is indefinite because it covers measurement techniques that yield different results and alter the scope of "average particle size."

Every reference that compares different measurement techniques also warns that different techniques generate different distributions. For example, Rawle cautions that "each characterisation technique will measure a different property of a particle (max. length, min. length, volume, surface area, etc.) and therefore will give a different answer from another technique which measures an alternative dimension." (Ex. 6, p. 2.) Similarly, Horiba observes: "Shape factor causes disagreements when particles are measured with different particle size analyzers. Each measurement technique detects size through the use of its own physical principle." (Ex. 7, p. 2.) Thus, while many different measurement techniques are used and accepted, for any given application of average particle size, the measurement technique needs to be specified, or at least reasonably ascertainable, so that meaningful comparisons can be made. In the context of the '723 patent, a measurement technique must be defined in order for the claimed average-particle-size range to fix the boundaries of the claim.

1. Kyowa's shifting positions on whether "average particle size" is fixed to one, three, or all measuring techniques supports a recommendation of indefiniteness.

As noted above, in the EPO opposition involving the same patent specification, Kyowa and its experts argued that, by specifying a measurement technique, the specification clearly identified the meaning of average particle size ("volume-weighted") and the method for measuring it ("laser diffraction"). But, upon completing infringement-related discovery in this litigation, Kyowa twice changed its position to encompass multiple measurement techniques. Kyowa's latest positions defeat the public-notice function of the claims, rendering them indefinite, because they effectively broaden the claimed average-particle-size range.

The first of Kyowa's changes broadened its pre-litigation construction to encompass three different techniques that measure different properties of the particles and consequently generate three different distributions. (D.I. 68, Ex. A, p. 2.) Those techniques were (i) laser diffraction, which assumes that the spherical equivalents of measured particles are volume-equivalent spheres; (ii) sieving, which assumes that the spherical equivalents of measured particles have diameters equal to the second-largest dimensions of the particles; and (iii) image analysis, which assumes spherical equivalency based on a two-dimensional property of the particles' images, such as their lengths or surface areas. (Ex. 6, p. 5–8; Ex. 7, p. 2; Ex. 10, p. 2314, "The resulting particle size distribution may be different …."; Ex. 13, p. 3; Ex. 31, p. 20-7, "there are many different size distributions"; Ex. 29, p. 79:4–18.) Because amino-acid crystals are not spherical, the three measurement techniques generate three different size distributions.



(Ex. 3 at KHB_0000401, taken from the clearer photos in the ’723 file history)

For example, sieving the rectangular crystals in the photos above would yield smaller spherical equivalents than laser diffraction because sieving generates a mass (or volume) distribution from the second-largest dimension of the particles, and laser diffraction generates a volume (or mass) distribution from the volume of the particles. (Ex. 29, p. 85:16–19; 97:20–98:9.) Similarly, Dr. Doherty’s image-analysis measurements resulted in a particle size of 81 μm, which is a 26% deviation from the 110 μm value in Fig. 1, and his image-analysis measurements resulted in a specific surface area of 0.05 m^2/cm^3, which is a 29% deviation from the laser-diffraction result of 0.07 m^2/cm^3 reported in Fig. 1. (Ex. 29, p. 31:4–11, Ex. 36, providing measurements that can be plugged into the particle-size and specific-surface-area formulas of record.)

And Kyowa’s latest claim-construction change goes even further: By not specifying any measurement technique, it encompasses all. Thus, Kyowa seeks even more freedom to move the goal posts after the ball is in the air, in complete disregard to the notice function that the patent is supposed to provide to the public. And, if that isn’t Kyowa’s intent, and all measurements are equal, the question arises once again: Why doesn’t Kyowa simply adopt its pre-litigation, EPO claim construction, which tied the average particle size to laser diffraction? In fact, by refusing even to concede that the measured particles are treated as volume-equivalent spheres, Kyowa telegraphs its intent to retain flexibility to change the scope of the claims by calculating the average particle size from an unlimited array of measured properties. (Kyowa Br., p. 19.)

In order to downplay this problem, Kyowa will have to rely on Dr. Doherty, who will presumably argue that all measurement techniques will yield the same result because amino acids are nearly spherical (in spite of the irregular and needle-like forms in Fig. 1 of the patent). But Dr. Doherty already showed that the measurement technique does matter because “the safest way

of measuring the number distribution is to do image analysis," which implies that other techniques would yield different results. (Ex. 29, p. 83:13–23.)

Thus, Kyowa's construction runs afoul of the public-notice function of the patent and renders the claims indefinite. When considering claimed properties like average particle size, "[t]he question is whether the existence of multiple methods leading to different results without guidance in the patent or the prosecution history as to which method should be used renders the claims indefinite." *Dow Chem. Co. v. Nova Chems. Corp. (Can.)*, 803 F.3d 620, 634 (Fed. Cir. 2015). Even if one of ordinary skill in the art can determine which method is "most appropriate," a patent is indefinite if its claims, when viewed in light of the specification and prosecution history, fail to guide one of ordinary skill in the art to one of the relevant measure. *Id.* at 634–35.

The public-notice function is particularly important in this case because the differences in the measured properties used by different measuring techniques are material to whether the measurement results fall within the claimed range.[3] Unless the Court associates the claimed average-particle-size range with a particular measurement technique, like Kyowa's own experts did prior to the litigation, the claims are invalid and the claim-construction decision should include a recommendation of indefiniteness.

2. Kyowa's assertion that the patent specification discloses multiple techniques for measuring particle size is not supported.

The '723 patent does not describe any technique for calculating the average particle size and describes only one technique that can be used for measuring average particle size—laser diffraction. As previously explained, that is how Kyowa interpreted the patent prior to taking

[3] For example, the sole documented instance where the D[1,0] value of Ajinomoto's seed crystals fell within the claimed range of 7–50 μm (the relevance of this measurement is disputed for reasons unrelated to claim construction), [redacted]. (Ex. 33, p. 25, 37.) Unsurprisingly, another measurement on the same day was outside of the claimed range. (*Id.*) And, of course, the larger D[4,3] values are well outside of the claimed range.

discovery from Ajinomoto in this litigation. (Ex. 11 at KHB_0000437–39.) Kyowa now takes a broader position, that "average particle size" covers all measurement techniques. In support of this position, Kyowa asks the Court to believe that, "[i]n addition to [the disclosure of crushing crystals], the specification provides several other disclosures about how to determine particle size." (Kyowa Br., p. 22.) There is absolutely no basis in fact for that statement. The specification describes a single measurement technique, laser diffraction. There is no description of sieving or image analysis to measure average particle size.

With respect to sieving, Kyowa blurs the distinction between milling seed crystals to make them smaller and sieving seed crystals to measure them. (Kyowa Br., p. 20–21.) The patent's milling examples describe crushing larger crystals into smaller crystals, but they do not explain how the average particle sizes of the original crystals or the crushed crystals were measured. (Col. 8:11–32.) The milling example in the patent merely uses a single, large screen, either 1000 μm or 300 μm, on the mill (Ex. 29, p. 95:5–10), and Dr. Doherty and Dr. Myerson agree that the patent fails to explain how the 11-μm and 45-μm seed crystals generated by the mill were measured. (Ex. 29, p. 103:14–18; Ex. 32, p. 204:3–15, 217:25–218:10.) In fact, even with the aid of confidential instruction manuals for the mill (Ex. 34; Ex. 35), Dr. Doherty (i) could not determine how the mill screen was used in the '723 patent (Ex. 29, p. 96:3–5), (ii) denied any understanding of what the screen sizes meant (Ex. 29, p. 94:21–96:2), and (iii) admitted that "[y]ou cannot" measure average particle size with a single screen. (Ex. 29, p. 93:4–16; 94:15–20.) Thus, Ajinomoto's construction does not "read out" this method of obtaining seed crystals, as Kyowa suggests, because Ajinomoto's construction describes how the seed crystals are *measured*, not how they are obtained. (Kyowa Br., p. 21.)

Further, sieve analysis is incompatible with crystals smaller than 20 to 30 µm because of limitations on sieve-screen size. (Ex. 6, p. 5, setting the useful sieving limit at 38 µm; Ex. 32, p. 103:9–20, setting the sieving limit at 20 to 30 µm.) Thus, a skilled artisan would not have expected that sieving was used to measure either the 11-µm size of the milled crystals or the patent's preferred seed-crystal sizes (col. 6:1–2.), including the claimed 7–50 µm range.

With respect to image analysis, the '723 patent does not mention or imply the use of image analysis to determine average particle size. Kyowa's position that Fig. 1 of the '723 patent discloses a method of determining particle size using image analysis is based simply on the fact that the patent provides a scale for the photographs. (Kyowa Br., p. 22.) While the photos may show the shape and approximate size of the crystals, one of ordinary skill in the art would never conclude that the photos are intended to convey the average particle size because Fig. 1 also includes a row of numerical values labeled "Particle size of crystals added (µm)" and the patent's description of the drawings expressly states that "Fig. 1 shows the relationship between the *average particle size*, specific surface area and total surface area of the crystals … added." (Col. 2:60–64, emphasis added.) This demonstrates, along with all the other average-particle-size quantities in the patent, the patent's intent to convey average particle size through the numbers in Fig. 1, not the photographs.

Simply put, there is no guidance in the '723 patent leading one of ordinary skill in the art to conclude that "the specification provides several other disclosures about how to determine particle size," as Kyowa urges.

3. The specification only discloses one way to measure particle properties—laser diffraction—and unless "average particle size" is determined by laser diffraction, the claims are indefinite.

The '723 patent discloses only one means by which particle size can be measured. (Col. 8:33–40.) Indeed, the patent's specific-surface-area measurements are just an alternative way to

express the D[3,2] average particle size because specific surface area equals six divided by the surface-area mean, D[3,2]. Further, those measurements were taken with an LMS-24 laser-diffraction device, which first calculated a volume distribution from which all 22+ average particle sizes could have been obtained. (Ex. 14, p. 30–31; Ex. 32, p. 198:7–24.) There is no reason why one of ordinary skill in the art would have used a different measurement technique to obtain either D[4,3] or D[1,0] when the particle-size distribution had already been obtained using laser diffraction. (Ex. 32, p. 198:7–199:13.) And this is exactly what Kyowa and its experts concluded prior to obtaining discovery in this lawsuit: One expert opined that laser diffraction is implied from the patent's use of laser diffraction for specific surface area (Ex. 11 at AJ110509–511), and the other opined that "particle sizing was done by laser diffraction" (*Id.* at AJ110469). Relying on its experts, Kyowa previously argued that, although the specification only mentions laser diffraction for measuring specific surface area, "it is clear to those skilled in the art that at the same time the average particle size is determined as *this is necessary* for the calculation of the surface area." (*Id.*at AJ110437, emphasis added.) For this reason and other reasons already discussed, one of ordinary skill in the art would understand that the average particle size in the patent is determined by laser diffraction.

While Kyowa argues that additional disclosures are made through references cited by the patent (Kyowa Br., p. 22), it is legally impermissible to read disclosures into the patent absent a proper incorporation by reference. "To incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents." *Cook Biotech, Inc. v. Acell, Inc.*, 460 F.3d 1365, 1376 (Fed. Cir. 2006) (quotations and citations omitted). While references cited on the face of the patent are part of the intrinsic record and can be useful for construing claims,

they are not incorporated by reference into the patent unless the patent specification contains an express statement identifying the material that is incorporated by reference. Thus, the disclosure of various measurement techniques in the references cited on the face of the ’723 patent does not constitute an incorporation of those techniques into the disclosure of the ’723 patent. There is only a single technique described in the ’723 patent that can be used to analyze particle size, and the claim term “average particle size” must be associated with that technique to comply with the definiteness requirement of 35 U.S.C. § 112(b). (Ex. 32, p. 219:10–23.)

As previously discussed, each method of measuring particle size yields a different result because it relies on a different physical property of the measured particles to calculate the diameters of equivalent spheres. Kyowa’s response is to analogize the current situation to measuring the speed of a car where choice of measurement technique is irrelevant. (Kyowa Br., p. 23–24.) That analogy falls apart because the speed of a car is always determined by the same properties, distance per unit of time. This is not the case with average-particle-size measurements because there is no single standard and different techniques determine the size of equivalent spheres based on different properties of the measured particles, e.g., second-largest diameter, volume, or projected surface area. According to the literature cited on the face of the ’723 patent, each technique for measuring particle size may be reliable on its own but each will yield different results relative to other techniques. (Ex. 6, p. 3; Ex. 7, p. 14, “different particle sizing techniques will produce different results for a variety of reasons including: the physical property being measured ….”.) Further, even converting from the distribution generated by one type of measuring device to another distribution can introduce error, for example, if sieving or laser diffraction results are converted to a number distribution. (Ex. 6, p. 3; Ex. 7, p. 9; Ex. 39, p. 18, 26.) With such device-dependency, claims 1 and 2 of the ’723 patent would be rendered

indefinite if open to any reliable measurement technique.

D. At most, Kyowa's arguments support a finding of indefiniteness because the volume mean diameter, D[4,3], cannot be ruled out with reasonable certainty.

Independent of the issue of whether the '723 patent sufficiently guides one of ordinary skill in the art to a particular measurement technique, the claims are also indefinite if the '723 patent fails to sufficiently identify which of the 22+ possible average particle sizes applies to the claims. Kyowa readily admits that different ways of determining "average particle size" can result in "wildly different results." (Kyowa Br., p. 7.) Nevertheless, it appears to seek refuge from indefiniteness under the general proposition that a patent need not expressly disclose information that is already well-known in the art. (Kyowa Br., p. 24.) While this is true, it does not resolve the issue of which average particle size a skilled artisan would select as there are at least 22 possibilities, including the volume mean diameter, which Kyowa admits is one of the two most important weighted averages. (Kyowa Br., p. 8.) Unless the Court determines that one of ordinary skill in the art could reasonably ascertain that a particular average particle size applies to the claims, then the claims are indefinite.

As already observed, Kyowa has no intrinsic evidence to support its proposed construction that the average particle size calculation is the sum of diameters divided by the number of particles, *i.e.*, the arithmetic mean or D[1,0]. On the other hand, the particle-size values in Fig. 1, the photograph in Fig. 1 that Dr. Doherty analyzed, and the references cited in the file history constitute intrinsic evidence that the average particle size is the volume mean diameter, D[4,3]. Particularly in view of Kyowa's pre-litigation claim construction positions, which comport with Ajinomoto's constructions, any evidence that Kyowa relies upon to oppose Ajinomoto's claim construction is, at best, evidence of indefiniteness.

In this regard, Kyowa's expert, Dr. Doherty, could not address Ajinomoto's supporting

evidence without retreating to the safety of responding that the '723 patent is confusing or lacks adequate description. There are numerous examples:

- "I was confused about Figure 1, about the second row in particular in Figure 1. It wasn't clear to me what those numbers meant." (Ex. 29, p. 94:18–20.)
- Regarding whether the '723 patent uses laser diffraction to make a spherical approximation of the particles: "It does not specify a method for doing that." (Ex. 29, p. 21:16–20.)
- When asked whether Fig. 1 shows an average particle size of 110 µm for Experiment 4: "I actually have formed no opinion about what that row of numbers means." (Ex. 29, p. 31:24–32:8.)
- When asked whether he thought that a spherical approximation was used to determine the size of the seed crystals in the '723 patent: "I cannot tell from the patent what – for instance, in Figure 1, what that second row of numbers refers to. … I do not know whether the authors of the patent intended that to be restricted to a spherical approximation or not." (Ex. 29, p. 73:10–23.)
- When asked if he could draw any conclusions from his calculations about the particle size of crystals added: "No." (Ex. 29, p. 77:13–16.)
- When asked what additional information he would need to derive the average particle size for the experiments in Fig. 1: "I don't know." (Ex. 29, p. 77:21–23.)
- When asked how the seed-crystal sizes in Fig. 1 were obtained: "I don't know how they were obtained, and I don't know what they mean, so I've not been able to form any opinion about that row of numbers in Figure 1." (Ex. 29, p. 109:5–11.)
- When asked if the '723 patent was invalid if the average particle size could not be ascertained with reasonable certainty: "No. The patent does not instruct on how to calculate the size or size distribution." (Ex. 29, p. 109:12–110:2.)

The most striking aspect about Dr. Doherty's testimony is his inability to discern what the key phrase "particle size of crystals added" means in Fig. 1. If taken as true, this is powerful evidence that the claims are indefinite in the absence of intrinsic evidence to guide one of ordinary skill in the art to a particular average particle size out of the 22+ possibilities.

There is also a problem in trying to apply Kyowa's construction to a wide distribution of particles. The sum of diameters divided by the number of particles, D[1,0], is more sensitive to changes in the number of smaller particles than the volume mean diameter, D[4,3]. (Ex. 29, p.

58:16–19.) Kyowa's example in its opening brief demonstrates that the smallest particles in the distribution affect the value of D[1,0] significantly and affect the value of D[4,3] minimally. (Kyowa Br., p. 18.) Consequently, the size detection limit of the measuring equipment (the smallest particle that the equipment can detect) determines how many of the smallest particles are included in the distribution, which will significantly affect the D[1,0] value. This was also confirmed by Dr. Doherty:

> Q. The number of small particles that you detect is going to affect the calculation for the arithmetic average, right?
>
> A. Yes.
>
> (Ex. 29, p. 88:24–89:3.)
>
> Q. Just more generally, the lower the size detection limit, the more smaller particles are going to be included in the particle size distribution that's calculated.
>
> A. If you have particles that small, that's true. …
>
> (Ex. 29, p. 92:10–15.)

Thus, measuring equipment with greater resolution pulls the D[1,0] down, and measuring equipment with lower resolution pulls the D[1,0] value up. (Ex. 32, p. 51:13–52:8; 108:9–109:2.) This is another example where Kyowa's construction results in indefiniteness because the size detection limit of the selected measuring equipment determines the scope of the claims.

The actions of Kyowa's own inventor, Ryo Ohashi, also suggest that the patent is indefinite. In 2017, Ohashi submitted a declaration in the EPO proceedings to show that the patented method could be applied to other amino acids besides L-glutamine. His declaration reports the results of his experiment in a table with row headings identical to the row headings of the table in Fig. 1 of the '723 patent. (Ex. 11 at AJ110611.) On page 2 of Ohashi's declaration, he indicates that the "average particle size[s]" of the added crystals in his table are "no addition, 16.5 µm, 245 µm," which correspond exactly to the entries beside the row heading "Particle size of crystal added (µm)" in the table. (Ex. 11 at AJ110610–11.) This confirms that one of ordinary skill in the

art would understand that "Particle size of crystal added" is the average particle size, but it also suggests indefiniteness because the inventor selected a third measure of average particle size, D[3,2], instead of either party's claim-construction proposal. This is evident from the formula for specific surface area which is equal to 6 divided by the D[3,2] average particle size. Using that relationship, one can verify with a calculator, as Dr. Doherty did, that Ohashi used the surface area mean size, D[3,2], to report average particle size. (Ex. 29, p. 106:15–108:9.)

This is true for both average particle sizes reported by Ohashi, and it's also true for four additional examples of testing performed by another Kyowa employee, Hidehiro Sugiura. His "average particle size[s]" of 44, 66, 89, and 148 yield the specific surface area values of 0.14, 0.09, 0.07, and 0.04 in his measurements. (Ex. 11 at AJ110604–06.)[4]

Understandably, Dr. Doherty was upset by this revelation, and he denied that there was any significance to the measurements:

> Q. Does the result of the calculation we just did inform you that the particle size of crystal added in that column which equals 16.5 is D[3,2]?
>
> A. No.
>
> Q. If it were D[3,2], would you expect that dividing 6 by D[3,2] would give you the specific surface area?
>
> A. Yes.
>
> Q. Isn't that what we just got?
>
> A. Complete coincidence, as far as I'm concerned. …
>
> (Ex. 29, p. 108:10–21.)

While Ohashi's and Sugiura's use of the D[3,2] average-particle-size value does not agree with either Ajinomoto's or Kyowa's claim constructions, their declarations show that scientists in the field (one of whom is an inventor, no less) would use what Kyowa calls a "weighted

[4] By the time of his deposition in 2019, Ohashi had switched to Kyowa's litigation position that the "average particle size" in the patent is "all of the size of the particles divided by the total number." (Ex. 12, p. 140:18–141:19.)

average" instead of D[1,0] to measure and report the size of seed crystals in the context of the same patent disclosure. It further demonstrates that the patent specification, which is identical to the one at issue in the EPO proceedings, led different scientists to different conclusions about the meaning of "average particle size." Had Ohashi and Sugiura checked the specific-surface-area values against the average-particle-size values in Fig. 1 of the patent specification, they should have understood that the average particle sizes are much larger than, and therefore cannot be, the D[3,2] average particle size. (Myerson Decl. ¶ 53.) This is evidence that the claims of the '723 patent are indefinite to the extent that one of ordinary skill in the art would not think to compare the particle-size and specific-surface-area values in Fig. 1 of the '723 patent (as Kyowa must argue in its answering brief because that comparison eliminates both D[1,0] and D[3,2] as average-particle-size candidates).

Accordingly, any evidence or argument that Kyowa applies in opposition to Ajinomoto's construction is, at most, supportive of a finding of indefiniteness.

E. The patent specification leaves no doubt that "adding crystals … to the medium … before crystals … deposit" refers to putting crystals in the medium and not the crystals that nucleate in the medium.

All of the intrinsic evidence supports Ajinomoto's construction of the adding step. The words of the claim exclude the possibility that adding crystals could possibly include the crystals that deposit or nucleate in the medium because, as Kyowa points out, the "purpose of this claim limitation is to require the seed crystals be added before the solution starts to nucleate." (Kyowa Br., p. 27.). And, the patent specification's numerous examples consistently describe the added crystals as pre-prepared crystals that are external to the medium so that their size and quantity can be controlled. Because the intrinsic evidence addresses this issue of claim construction, it is improper to consider extrinsic evidence contradictory to that claim construction. *Phillips v. AWH*

Corp., 415 F.3d 1303, 1317 (Fed. Cir. 2005). But, extrinsic evidence, primarily in the form of expert testimony, is all that Kyowa can offer.

1. "Adding crystals … to the medium" does not equate to nucleation or breaking crystals apart.

To support its proposed construction, Kyowa relies entirely on extrinsic evidence: dictionaries, Dr. Doherty's declaration, and one technical reference. The absence of citations to the patent or file history is not accidental as the intrinsic evidence contradicts every one of Kyowa's arguments. Kyowa first avers that a person of ordinary skill in the art would understand the "adding" step to encompass four possible methods: (1) physically pouring, (2) slurry, (3) secondary nucleation, and (4) shock seeding. Tellingly, the patent does not mention secondary nucleation or crystal breakage, pressure waves, ultrasonic or mechanical disruption, or shock seeding. And, while Kyowa cites to Mullin's *Crystallization* book to identify different ways to provoke nucleation (Kyowa Br., p. 4, "agitation, mechanical shock, friction, and extreme pressures"), Mullin never equates nucleation to seeding or adding crystals to a solution. (*See also* Ex. 32, p. 158:8–25; 159:16–160:25, explaining why shock seeding is a type of nucleation that would not be compatible with a fermentation process; 162:5–16.)

Most importantly, the plain language of the claims prevents the adding step from encompassing secondary nucleation and crystals breaking within the medium. Secondary nucleation and breakage result from the crystals that are *already present in* the medium. But, the claim language requires adding crystals *to* the medium, and every example in the patent confirms that adding refers to putting external crystals into the medium. Neither secondary nucleation nor crystal breakage constitutes adding crystals *to* the medium.

The '723 patent says absolutely nothing to lead one of ordinary skill in the art to believe that the claimed step of "adding crystals of the amino acid having an average particle size of 7 to 50

µm *to the medium*" should somehow encompass any form of nucleation or breakage of crystals *within the medium*. Even though nucleation is inherently occurring within the medium (Ex. 29, p. 99:10–21, 115:15–18, 120:24–121:4), the patent never addresses how nucleation or crystal breakage would factor into the calculation of the average particle size. Similarly, the "Addition amount" values of 5.5 g/l in Fig. 1 reflect the amount of crystals that were externally "obtained" and "used as the crystals to be added to the medium." (Col. 9:66–10:1.) On the other hand, the blank "Addition amount" entry for the Control experiment in Fig. 1 reflects the fact that none of the crystals that grew and accumulated in the medium were considered "added" crystals.

As a practical matter, it would not even be possible to apply Kyowa's construction if the average particle size included both the crystals that are put in the medium and the crystals that nucleate or break within the medium. Dr. Doherty explained that fermentation mediums, including the one described in the '723 patent, are continuously mixed, and consequently, secondary nucleation never stops. (Ex. 29, p. 118:13–22.) This would mean that, under Kyowa's construction, the adding step never stops for as long as the fermentation process continues. And, there would be no means of ascertaining the average particle size of added crystals because all the crystals in the medium would be growing at the same time that new crystals are nucleating and breaking apart. (Ex. 29, p. 116:17–21.)

When confronted with the problem of trying to include secondary nuclei in the calculation of average particle size, Dr. Doherty stumbled. He first said that crystals formed through secondary nucleation should be included in the calculation "If that's your primary means of creating seeds." (Ex. 29, p. 125:23–126:12.) But, he was unable to explain ("I don't have an opinion on that") what crystals should be considered in the average-particle-size calculation when secondary nucleation is not the primary means of creating seeds. (*Id.*) Similarly, even if secondary

nucleation was the primary method of creating seeds, Dr. Doherty had no explanation ("I actually haven't formed an opinion on that") for how average particle size would be calculated when both externally-created crystals and nucleated crystals were present in the medium. (Ex. 29, p. 126:13–127:7.) Accordingly, there is no reason why one of ordinary skill in the art would interpret "adding crystals … to the medium" as anything other than putting crystals into the medium.

That conclusion is consistent with Kyowa's dictionary definitions. (Kyowa Br., p. 25.) For example, *Webster's* defines "addition" as "direct chemical combination of substances into a single product." This chemical definition of addition entails combining one substance with another, which is not particularly relevant to the patent but is more akin to putting seed crystals into a medium than it is to breaking crystals apart. Similarly, *The New Oxford American Dictionary* offers the example "a new wing was *added to* the building." In that example, a new structure is put on the existing building which is analogous to putting crystals in the medium, not the nucleation or breakage of amino acids that are already part of the medium. Thus, even considering the different, isolated forms of the word "add" in Kyowa's dictionaries, Ajinomoto's construction is the best fit. (*See also* Ex. 32, p. 80:20–24, defining "seed.")

As a last resort, Kyowa quotes deposition testimony of Ajinomoto's corporate witness on the subject of the accused process. Aside from the improper reliance on the description of the accused process to define the claim term, the witness's testimony doesn't support the proposition for which Kyowa offers it. The witness was not asked how Ajinomoto adds crystals to the fermentation medium; he was asked [redacted] (D.I. 83, Ex. I, p. 320:20–24, emphasis added). In other words, the witness never testified that [redacted]

[redacted]

2. The specification defines "before crystals of the amino acid deposit in the medium" to refer to the "presence" of crystals with one exception for the deposition of a "slight amount" of crystals.

Where a patentee opts to become "his own lexicographer," the definition in the specification applies to the term in the claim, and in this case, it also helps to rectify the problems caused by Kyowa's construction of "adding." *See Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). Under Ajinomoto's construction of adding, it is not necessary to construe the "before …" phrase in the first place because the average-particle-size calculation is based on the crystals as they exist before they are added to the fermentation medium—just like every example in the '723 patent. Under Kyowa's proposed construction of "adding," the calculation becomes overly-complicated because it must also account for the nucleation, breakage, and growth of the amino acid already present in the medium.

Although the patent never contemplates Kyowa's calculation, in the context of putting seed crystals in the medium, it defines the claimed phrase as the time period "during which the presence of amino acid crystals is not observed at all in the medium," with the exception of a slight amount that might deposit. (Col. 6:43–49.) Since the first seeding process (disregarding nucleation of a slight amount of crystal) would cause the presence of amino acid crystals, the first means of adding seeds is the one that is relevant to the average-particle-size calculation. This is generally consistent with Dr. Doherty's opinion that the "primary means" of seeding is the one that is relevant to the average-particle-size determination (Ex. 29, p. 125:23–126:20), and it avoids the conundrum of how to calculate average particle size when crystal growth, breakage, and nucleation are simultaneously occurring within the medium, contrary to Kyowa's position that Ajinomoto's construction makes it impossible to practice the patent.

Kyowa tries to evade the definition of "before …" in the specification by redefining it. (Kyowa Br., p. 27.) There is no evidence, aside from Dr. Doherty, to support Kyowa's assertion that "presence" and "deposit" are synonyms. To the contrary, the specification uses the word "however" to indicate that "deposit" is an exception to "presence." (Col. 6:46–49.) And one of ordinary skill in the art would understand that the presence of any crystals will cause the amino acids in the supersaturated solution to adhere to those crystals (Kyowa Br., p. 3), irrespective of whether such a result is desired and irrespective of whether those crystals result from nucleation within the medium or the addition of crystals to the medium. Thus, except for a slight amount of crystal deposition, the adding step must begin before any crystals are present in the medium, and the average-particle-size calculation is based on the size of the crystals "to be added," consistent with the definition and examples in the patent specification.

Conclusion

Because Ajinomoto's proposed constructions are supported by the intrinsic record and consistent with the most relevant extrinsic evidence, the Court should adopt Ajinomoto's proposed constructions, or with respect to the "average particle size" term, make a recommendation that claims 1 and 2 of the '723 patent be found invalid as indefinite.

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